

**Congress of the United States**  
**Washington, DC 20515**

***Can FDA Handle the Burden of H.R. 4167?***

March 6, 2006

Dear Colleague:

Today, the Food and Drug Administration is struggling to meet the many demands placed on the agency. FDA has been beset by high profile recalls of blockbuster drugs, enormous backlogs in the agency's approval of generic drugs, new threats of terrorist attacks on the food supply, and the urgent need to prepare for a possible pandemic flu. Compounding these challenges, FDA has had a confirmed commissioner for only 18 months since 2001 and is currently functioning under an acting commissioner who can work only part time because he also serves as Director of the National Cancer Institute.

At a time when FDA's ability to handle its current workload is so clearly in question, H.R. 4167 would impose even more demands on this overburdened agency.


According to the Congressional Budget Office, if H.R. 4167 is enacted, FDA would be forced to review during the first year alone 200 petitions from states requesting FDA's permission to maintain or pass state food safety laws. CBO estimates that FDA will have to spend \$400,000 on each petition at a cost of over \$100 million over the course of five years. In its report, CBO describes the very restrictive time limits for FDA's review of these petitions and, consequently, "assumes that FDA would not be able to fully comply with the time limits imposed under the bill."


Congress has never heard FDA's views on whether it can handle the increase in its workload created by H.R. 4167 because there has never been a hearing on this legislation. What we do know from FDA, however, is that in order to deal with a host of other demands, like preparing for the flu pandemic and improving drug safety, FDA's budget proposal would cut the food safety staff by 86 full-time employees in the next fiscal year. Yet it is the food center that would be charged with responsibility for carrying out the mandates of H.R. 4167. Additionally, the Center on Budget and Policy Priorities estimates that the Bush budget proposals will result in a cut of over \$400 million in funding for the Department of Agriculture's Food Safety Inspection Service.

The states currently carry out 80% of the food safety work today. According to the Association of Food and Drug Officials, FDA relies upon the states' work in this area and often seeks the states' assistance in dealing with imminent health hazards. Since there has never been a hearing on this legislation, there is no evidence that the current system is not working or that states need any additional assistance from FDA. On the other hand, there is abundant evidence that FDA lacks the resources and leadership to shoulder the full burden of protecting the nation's food supply.

At a time when funding for our federal food safety programs is being systematically cut, H.R. 4167 would mandate that FDA take on a host of additional responsibilities—without providing for any new sources of funding. This makes no sense and I urge you to oppose it when it goes to the House floor this week. For more information, please contact Greg Dotson or Rachel Sher of Rep. Waxman's staff (5-3976).

Sincerely,

  
DIANA DeGETTE  
Member of Congress

  
HENRY A. WAXMAN  
Member of Congress